APPENDIX F: REGULATORY COSTS ON A PER-PRODUCT BASIS

This appendix provides a description of the data, costs, and modeling scenarios that are used to examine the effects of regulation on innovation. The material presented here supports information discussed in Chapter VI. The organization of this appendix is as follows:

- Section A: Introduction -- Provides an explanation of the estimates used to predict total regulatory costs for the development of a single commercial product.
- Section B: Examination of Submissions -- Discusses information collected from companies that have conducted experimental field tests.
- Section C: Survey Data on Field Tests -- Presents information on field tests collected in the ICF Survey of Biotechnology Companies (ICF 1988).
- Section D: Discussions with Research Scientists -- Discusses information gathered from biotechnology research scientists regarding probable field test scenarios.
- Section E: Assessment of Costs of Multiple and Follow-on Submissions -- Compares the costs of multiple and follow-on R&D submissions for field tests to first time submissions.
- Section F: Per-product Cost Scenarios -- Describes the assumptions underlying the development of per-product costs.
- Section G: Measuring the Effects of Regulatory Burdens Using a Cash Flow Model -- Describes the assumptions used in the development of the cash flow model and how to interpret results.
- Section H: Modeling the Effects of Regulatory Requirements on Discounted Cash Flows -- Presents the results of eleven different regulatory cash flow scenarios.

A. Introduction

In assessing the potential impact of the rule on innovative activity, it is important to consider the total regulatory costs that must be incurred over the course of developing a single commercial product.

Chapter IV of this report presents estimates of the costs incurred by industry per submission to EPA; estimates of the total costs of the rule were made using these per-submission costs and the implicit simplifying assumption

that a firm will incur the costs of only the minimal number of submissions for each microorganism it brings to the market. This minimal number depends on the nature of the microorganism, its application, and the provisions of the regulations. In cases with new microorganisms used in fermentation-system applications, a single MCAN is required unless the microorganism is partially exempt from reporting under TSCA Section 5(h)(4). For microorganisms in environmental applications, at least one TERA is assumed to be needed when the product enters field testing, with a MCAN following at the point of commercialization.

While these simplifying assumptions are appropriate for many products, there are likely to be situations in which a larger number of submissions will be needed for a single commercial product. For example, an environmental application developed with the aid of a series of field tests may need a series of TERAs or major TERA modifications in addition to a MCAN before it may be marketed. Firms weighing the costs and benefits of developing new environmental application products will take into account the costs of the entire series of submissions they expect before proceeding with research.

Estimating the total regulatory costs per product is difficult for a number of reasons. First, no one has yet brought an environmental application recombinant microorganism in a market area covered by TSCA all the way through research, development, and field testing to the point of general commercial use. Thus, there are no complete case histories available to use as a basis for predicting how many field tests will be conducted, the number of microorganisms examined in each field test, or the number of sites at which tests will take place. Second, the numbers of microorganisms, tests, and sites will be expected to vary substantially from case to case depending on the application and on how well the early tests turn out. Third, costs per submission for the second and subsequent submissions involving similar

microorganisms at the same test sites are expected to be lower than the costs of the first submission in a project because much of the same information can be reused, but there is still uncertainty about how much lower the costs are likely to be. Finally, EPA's need for detailed submissions and monitoring may change over the course of each product's development as more is learned about the microorganism and its relationship to its environment.

EPA has tried to obtain a realistic picture of these uncertainties in a number of ways: through analysis of survey data; examinations of the few submissions relating to environmental application products received to date; informal interviews with individuals involved in the study of genetically modified microorganisms; and assessments of the degree to which the information in one submission can be reused in subsequent submissions. Because of the uncertainty evident in each source of information, no definite conclusions on total costs per product could be reached. However, EPA has constructed a number of plausible cases that are likely to cover many actual situations.

B. Examination of Submissions

In 1989, at least two firms had made submissions relating to field tests of recombinant products in TSCA areas. Monsanto has made a single voluntary submission and has performed one field test (PMN P87-1292). As of August 1989, BioTechnica International had submitted a total of 18 voluntary PMNs in five groups for different strains of two species of microorganisms, and had initiated five field tests involving eleven rDNA strains in pursuit of two commercial products.

C. Survey Data on Field Tests

The ICF survey requested information on numbers of field tests and numbers of microorganisms field tested per commercial product (ICF 1988; see Appendix A). Of the firms responding to the survey, 19 provided estimates of field tests and microorganisms. The small number of responses to these questions is not surprising, as many firms concentrate on fermentation-system applications that do not need field tests.

The respondents' estimates of the number of strains tested per commercial product (see Table F-1) ranged from 1 to 20, with a mean of 5.6 and a median of 4. The number of field tests per strain for these microorganisms ranged from 1 to 75, with a mean of 9.2 and a median of 5. Most of these responses (13 of the 19) were from firms with naturally-occurring microorganisms only, reflecting the limited extent of research into engineered microorganisms for environmental applications. The six firms doing at least some research into engineered microorganisms (including some physically and chemically mutated microorganisms used in research) indicated similar numbers of microorganisms and tests, as shown in the table. Because of the very small number of data points and the fact that some could refer to naturally-occurring products under development by the respondents, the figures in the table cannot be relied upon for an estimate of field test patterns.

More recently, in conversations with industry and university sources, the number of field tests per strain ranged between two and four (Appendix B). These estimates are used in the analysis in Chapter IV. Experiments with genetically engineered microorganisms are assumed to be toward the higher end of this range, while product based on naturally occurring microorganisms would be at the lower end (Appendix B).

Table F-1. Survey Responses on Numbers of Microorganisms and Field Tests Per Product

	All Responses	Responses from Firms with Engineered Products
Numbers of Responses	19	6
Numbers of Strains Tested Per Commercial Product		
Minimum	1	2
Maximum	20	12.5
Mean	5.6	6.8
Median	4	6.5
Numbers of Field Tests Per Strain		
Minimum	1	1
Maximum	75	12.5
Mean	9.2	6.3
Median	5	4.5

Source: ICF 1988.

D. Discussions with Research Scientists

In order to get information on likely field testing patterns over the course of product development, EPA contacted several research scientists familiar with the application of biotechnology to TSCA areas. Each was asked to suggest a plausible series of field tests leading to commercial products.

In general, those not actively developing biotechnology products for environmental applications felt unable to make even hypothetical predictions of numbers of field tests likely to be conducted. They emphasized the uncertainty involved in planning research programs, and related the actual number of tests to the outcome of the early tests, to the firm's ability to finance multiple tests, and to public demands (not necessarily from EPA) for thorough field testing to ensure safety before general commercial use in the environment.

Two individuals most directly involved in product development offered more specific assessments. In the area of bioremediation using recombinant microorganisms, Frank Mondello of General Electric speculated that only two or three field tests using one strain per test might be conducted in successive years before commercialization for a typical recombinant product designed to degrade hazardous wastes.

He reasoned that, because of the difficulty, publicity, and high cost associated with field tests, most development work would take place in the laboratory. Researchers would try to be virtually certain of success before bringing a product to the stage of field testing (Mondello 1990).

The small number of field tests projected for the bioremediation area may not be typical of all industry segments. Elizabeth Owens of BioTechnica projected that for a product in the agricultural area (specifically, nitrogen fixation microorganisms) the initial period of laboratory development would be followed by a series of field tests over three years (Owens 1990).

In the first year of field testing, several strains of a microorganism would be tested on a very small scale at perhaps three different sites. In the second year, this pattern would be repeated as the number of strains was reduced to a more promising group.

By the third year, the number of promising strains would be cut still further; the most promising strains would be put through large-scale field tests at five or more sites. Based on this scenario, a series of tests could involve eleven separate tests (tests at three sites in each of the first two years and five more in the last year) with multiple strains involved in an individual test.* Additional information on field testing patterns is presented in Appendix B.

E. Assessment of Costs of Multiple and Follow-on Submissions

Groups of strains using the same host species and tested at the same site are likely to be significantly less costly per strain than single, unique strains. Similarly, a series of related submissions will be less expensive per submission. BioTechnica estimated that two-thirds of the information in one submission can be reused in subsequent submissions (BTI 1989). For the purpose of constructing plausible estimates of per-product regulatory costs, it has been assumed that the first TERA submission and associated monitoring and CBI substantiation imposes the full cost (worst case scenario) of approximately $18,845 to $130,934 presented in Table F-2. Subsequent TERA submissions or major modifications costs are assumed to impose reporting costs only between $5,753 and $26,283. Additional sites added to a submission are assumed to cost an additional monitoring cost of $3,750 to $7,500 regardless of the number of strains. The cost of a submission is assumed not to be affected by the addition of closely-related strains to be field tested at the

* Depending on the wording involved, a field test could include one or more TERAs.

same time and at the same site, as much of the data presented for the first strain could be applied to the sections of the submissions related to the other strains.

F. Per-product Cost Scenarios

Using the assumptions presented above, two plausible cost-per-product scenarios for recombinant environmental application products have been constructed. The first represents a relatively high cost; it is modeled on a pattern of field tests similar to that projected by BioTechnica for nitrogen fixation products. It purposely assumes a relatively high unit cost per submission in order to show possible cost under pessimistic assumptions (see Table F-3). The second represents a recombinant environmental application product with low regulatory costs (see Table F-4); it is based on a small number of field tests such as that projected for a recombinant bioremediation product. It purposely assumes a relatively low unit cost in order to show costs under more optimistic assumptions.*

This cost may be compared to the upper bound of what BioTechnica estimated it had spent per product as of August 1989 (Owens, 1989). BioTechnica estimated that its total development costs for two products had been between $2,500,000 to $4,000,000, and that between 10 and 15 percent of the total had been related to submissions to EPA and EPA-required monitoring. Thus, BioTechnica estimated that it had spent up to $2,000,000 * 15% or $300,000 on regulatory costs per product. While this is below the high cost estimate here of about $390,954 BioTechnica's development process was not complete.

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* The assumptions of high and low unit costs per submission are for illustration only. They are not meant to imply that nitrogen fixation products will have higher costs per strain or per submission than bioremediation products.

Table F-2. Average Regulatory Submission Costs Per Product (Final Rule)

Regulatory Cost Item	Average Fermentation-system Application	Average Environmental Application
TERA Reporting Cost		$ 5,330 to $ 54,425
TERA Monitoring Cost	$ 12,500 to $ 75,000	
TERA CBI Cost		$ 1,015 to $ 1,509
Subtotal TERA Cost		$ 18,845 to $130,934
MCAN Reporting Cost	$ 7,219 to $ 32,772	$ 6,931 to $ 32,772
MCAN CBI Cost	$ 1,559 to $ 2,852	$ 1,104 to $ 1,984
Total Per-Product Cost	$ 8,778 to $ 35,624 $ 26,880 to $165,690	

Source: Appendix D.

Table F-3. High Cost Scenario for Regulated Product

Unit Cost Estimates:

Initial TERA Submission (first site):	$ 54,425
Monitoring:	$ 75,000
CBI substantiation:	$ 1,509
Initial TERA, Monitoring + CBI:	$130,934
Follow-on TERA Submission + Monitoring + CBI:	$ 26,283
Added Site + Monitoring:	$ 7,500
MCAN after TERA + CBI:	$ 34,756

Year 1 of Field Testing: Tests of Multiple Strains at Three Sites

Initial TERA	= $130,934 * 1 =	$130,934
Added Sites (2 Sites)	= $ 7,500 * 2 =	$ 15,000

Year 2 of Field Testing: Tests of Fewer Strains at Three Sites

Follow-on Submissions (3 Sites)	= $ 26,283 * 3 =	$ 78,849

Year 3 of Field Testing: Tests of Few Strains at Five Sites

Follow-on Submissions (5 Sites)	= $ 26,283 * 5 =	$131,415

Year 4: Commercialization

MCAN Following TERA	= $ 34,071 * 1 =	$ 34,756
	Total Cost =	$390,954
	Cost Per Strain if 20 Strains are Tested:	$ 19,548

Note: "Follow-on submission" means new TERA or major TERA modification. Costs are not discounted.

Table F-4. Low Cost Scenario for Regulated Product

Unit Cost Estimates:		
Initial TERA Submission:		$ 5,330
Monitoring:		$ 12,500
CBI Substantiation:		$ 1,015
Initial TERA, Monitoring + CBI:		$ 18,845
Follow-on TERA, Monitoring + CBI:		$ 5,753
MCAN after TERA + CBI:		$ 8,035
Year 1 of Field Testing: Test of One Strain at One Site		
Initial TERA	= $ 18,845 * 1 =	$ 18,845
Year 2 of Field Testing: Test of One Strain at One Site		
Follow-on TERA w/ Monitoring	= $ 5,743 * 1 =	$ 5,753
Year 3 of Field Testing: Test of One Strain at One Site		
Follow-on TERA w/ Monitoring	= $ 5,743 * 1 =	$ 5,743
Year 4: Commercialization		
MCAN Following TERAs	= $ 8,035 * 1 =	$ 8,035
	Total Costs =	$ 38,366

G. Measuring the Effects of Regulatory Burdens Using a Cash Flow Model

Firm behavior can be based on hypothetical rates of return, but rates of return also can be calculated by a simple cash flow model that incorporates expenditures that a firm incurs while developing a new product as well as the returns it anticipates. Within this framework, the potential effects of regulatory changes on expected returns can be explored.

Constructing a cash flow model necessitates developing the parameters and assumptions used to estimate the profitability of a project as measured by its net present value. In many cases, the data that would be needed to calculate realistic rates of return are not available; thus this model can be used at present for illustrative purposes only. The model must incorporate a mechanism through which regulation affects the profitability of potential projects.

The cash flow model used in this analysis has the following features and assumptions:

- Costs and revenues (net of the costs of manufacturing and selling the product) are estimated quarterly, for up to 25 years.
- The magnitude of the revenues for a given project can be varied.
- Revenues for each quarter are adjusted downward for perceived risk. Perceived risk is the chance that the product may not be successfully developed or may earn less than its expected return. Revenues per quarter are then calculated after an adjustment for risk. Risks could be lowered by various factors, including regulations that increase the social acceptability of biotechnology products.
- Revenues are expected to drop over time as the product becomes obsolete. The rate of decline can be varied from case to case, allowing comparisons between cases of rapid obsolescence (in which superior competing products are likely to appear within a few years) in comparison to products with long commercial lives.
- Product development is assumed to require 5 years; costs of product development are assumed to rise linearly from the start of the project through 20 quarters until the product is ready for

commercialization. The magnitude of the quarterly development cost can be changed readily.

- The profitability of a given project is measured using the net present value of the project when all cash flows are discounted at a fixed discount rate. (Alternatively, profitability can be measured using the "internal rate of return" (IRR), the discount rate at which the project would just break even).

To illustrate the use of the model, Figure F-1 shows the cumulative expected cash flow for a representative product over a time period of 25 years (100 quarters)*. For the case shown, the model assumes a development cost averaging $150,000 per quarter. Expected revenues after commercialization start at just under $173,000 per quarter, but decline at 10 percent per year due to obsolescence.** All costs and returns are discounted at 7 percent per year, the private real discount rate. At the R&D stage, cumulative net revenue steadily falls through the first twenty quarters. The greatest negative net revenue level is $3,000,000; this represents the total undiscounted cost of developing the product. At the point of commercialization, cumulative revenues begin to rise. This pattern is

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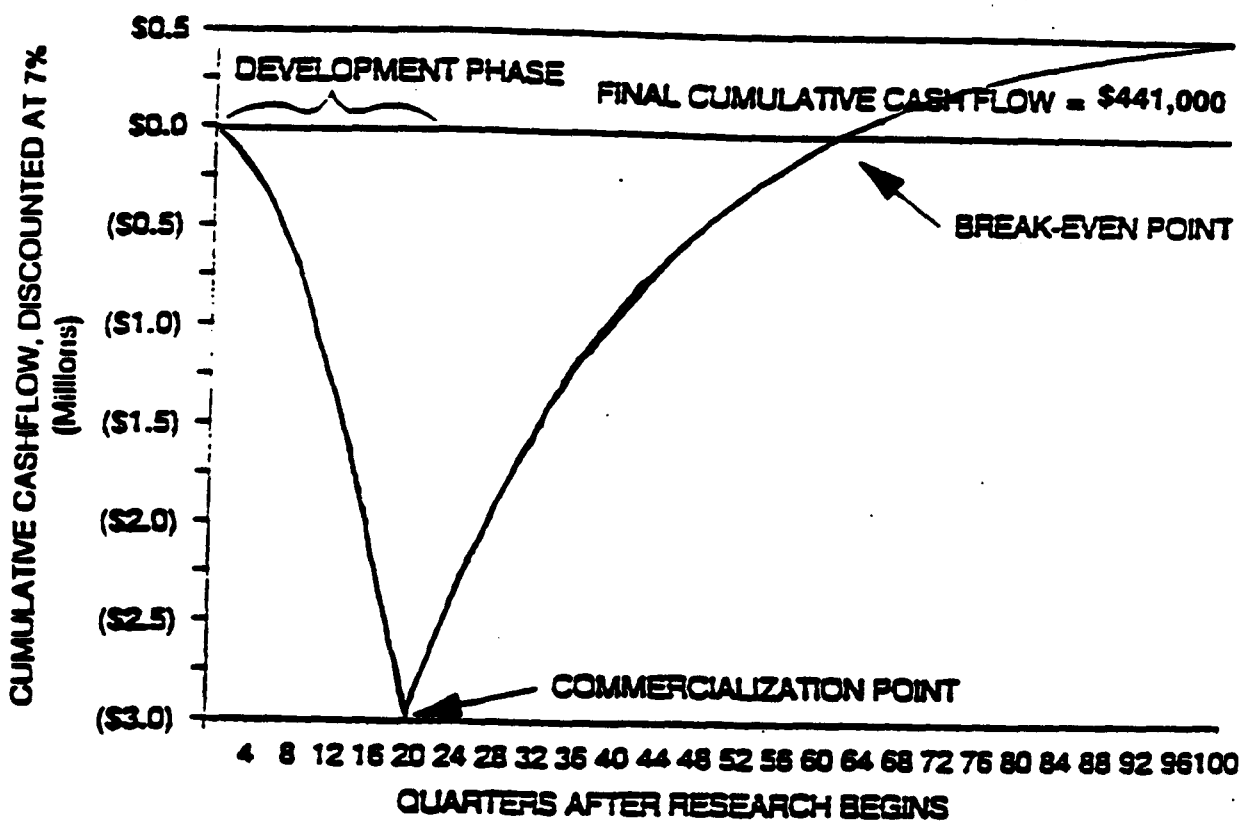
A long maximum product life span was chosen to allow an examination of the effects of different rates of obsolescence. The product used as an example is only marginally profitable, and thus will not represent more profitable products.

These cost and return values were set so as to result in total R&D costs of $3,000,000, and total expected net revenues after manufacturing costs, but before regulatory costs, of $6,000,000. The value for R&D costs, while hypothetical, is roughly in line with BTI's estimate that it has spent between $2,500,000 and $4,000,000 in its research into recombinant nitrogen fixation products. The firm expected the research to yield two commercial products, suggesting that between $1,250,000 and $2,000,000 have been spent per product. As research was not complete, total expenditures of $3,000,000 per product do not appear unlikely.

The values for R&D costs and expected revenues are also consistent with data from the ICF survey. Yearly R&D expenditures per product for firms with no naturally-occurring products averaged $558,000 per year, or almost $3,000,000 if extended over five years. The profit threshold sought by firms with no naturally-occurring products averaged approximately $6,000,000.

Figure F-1. Discounted Cash Flow



similar to the course of firm development described in Biotech 90: Into the Next Decade, a report on business and financial issues in the biotechnology industry. This report* showed startup firms falling further and further into debt before their products are ready for commercialization, and then rising into profitability after products are brought to market. The net present value (the sum of all returns minus all costs, discounted back to the present) for the project is calculated to be $441,000. This value can be read directly from Figure F-1 as the final value at the right-hand end of the cumulative discounted cash flow curve.

The project's profitability can also be measured by computing the internal rate of return (IRR), the discount rate at which the project would just break even. In this example, if the costs and returns for the project were to be discounted at 9.7 percent, the cumulative discounted cash flow would fall to zero. Thus, by definition the IRR is equal to 9.7 percent.

H. Modeling the Effects of Regulatory Requirements on Discounted Cash Flows

A simple model can show the effects of reporting costs, delays, and risks under various circumstances and for different product types. Several cases that suggest different decision-making on the part of affected firms are presented here as are the predicted changes on costs, delays, profits, and risks. The cases presented are summarized in Table F-5.

1. Case 1: Effects of Reporting Costs on a Non-exempt Environmental Application Project

The upper panel of Figure F-2 (Case 1) presents how the cumulative cash flow for a hypothetical project is affected by reporting costs. The figure presents costs for a marginally-profitable reportable microorganism

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* See Chart 68, Net Income (loss)--All Companies p. 104, Biotech 90: Into the Next Decade, G. Steven Burrill with the Ernst & Young High Technology Group, Mary Ann Liebert, Inc., New York, 1989.

intended for an environmental application. While the example is strictly hypothetical, EPA believes that the scale of development cost is plausible for a project of this type. The expected returns are assumed to be close to the minimum acceptable level. Examining a marginally profitable project yields a *worst-case* example of the effects of the regulations and should be interpreted as an illustration of the potential for impacts rather than a prediction for more typical situations (Case 5 shows that projects with greater returns are much more robust in the face of regulatory costs). Without regulation,* the project breaks even and covers its development costs by the 59th quarter; by the 100th quarter -- the time horizon for the analysis -- it provides a cumulative discounted cash flow (profits) of $441,000.

With regulation in place and assuming that this project requires large numbers of field tests for which TERAs will be filed, plus a MCAN at commercialization, the development costs rise. For this example, the analysis assumes that the total cost of reporting and controls would be equal to $390,000. This regulatory cost level is in line with, the estimate of per product costs for a high-cost case that was presented earlier, in which three series of field tests at a number of sites were assumed. As seen in the figure, these costs drive the cumulative cash flow even further below zero before commercialization. After commercialization, cumulative cash flow again rises, but never reaches the pre-regulatory level.**

The effects of guidance or voluntary reporting are not considered here.

The analysis assumes that regulation does not create market entry barriers that increase demand for approved products. Significant barriers would arise only if TSCA-regulated products competed mostly among themselves rather than against unregulated products or products regulated under other statutes.

Table F-5. Effects of Regulation on R&D Returns (Costs are in thousands of dollars)

Case	Without Regulation				With Regulation				
	Total Undiscounted Development Expense	Total Undiscounted Expected Returns	Net Returns Discounted at 7% Per Year	Internal Rate of Return	Total Undiscounted Reporting Costs	Rate of Obsolescence (Annual drop in returns)	Total Regulatory Delay in Quarters	Net Returns Discounted at 7% Per year	Internal Rate of Return
1. Reportable Released	$3,000	$6,000	$441	9.7%	$390	10%	0	$125	7.7%
2. Released with Delay	$3,000	$6,000	$441	9.7%	$390	10%	4	($331)	5.3%
3a. Large Released	$9,000	$18,000	$1,322	9.7%	$390	10%	0	$1006	9.0%
3b. Large Rel. with Delay	$9,000	$18,000	$1,322	9.7%	$390	10%	4	($360)	6.3%
4a. Small Released	$900	$1,800	$132	9.7%	$390	10%	0	($184)	4.2%
4b. Small Rel. with Delay	$900	$1,800	$132	9.7%	$390	10%	4	($320)	2.4%
5a. High Return Released	$3,000	$9,000	$1,855	17.2%	$390	10%	0	$1,539	14.7%
5b. High Return Rel. with Delay	$3,000	$9,000	$1,855	17.2%	$390	10%	4	$856	10.9%
6a. Rel., Rapid Obsolescence	$3,000	$4,579	$275	9.7%	$390	30%	0	($41)	6.6%
6b. Rapid Obsolescence, w/ Delay	$3,000	$4,579	$275	9.7%	$390	30%	4	($883)	-0.2%
7a. Rel., Slow Obsolescence	$3,000	$7,332	$578	9.7%	$390	2%	0	$261	8.1%
7b. slow Obsolescence, w/ Delay	$3,000	$7,332	$578	9.7%	$390	2%	4	($40)	6.8%
8. Rel., Low Regulatory Cost	$3,000	$6,000	$441	9.7%	$38	10%	0	$410	9.5%
9a. Contained	$3,000	$6,000	$441	9.7%	$35	10%	0	$416	9.5%
9b. Small Contained	$600	$1,200	$88	9.7%	$35	10%	0	$63	8.9%
10. Unregulated Product	$3,000	$7,000	$912	12.4%	$35	10%	0	$887	12.2%

Figure F-2: Effects of Reporting Costs (Case 1)

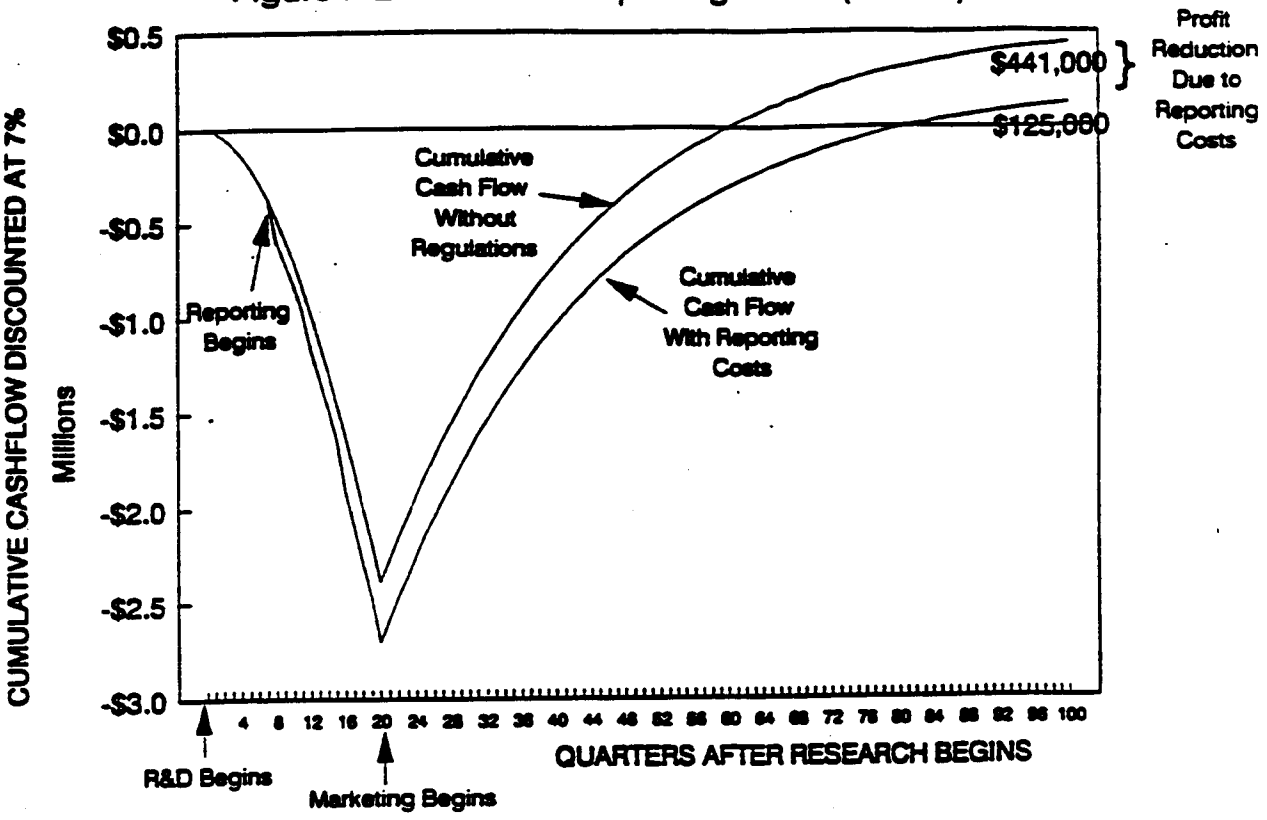
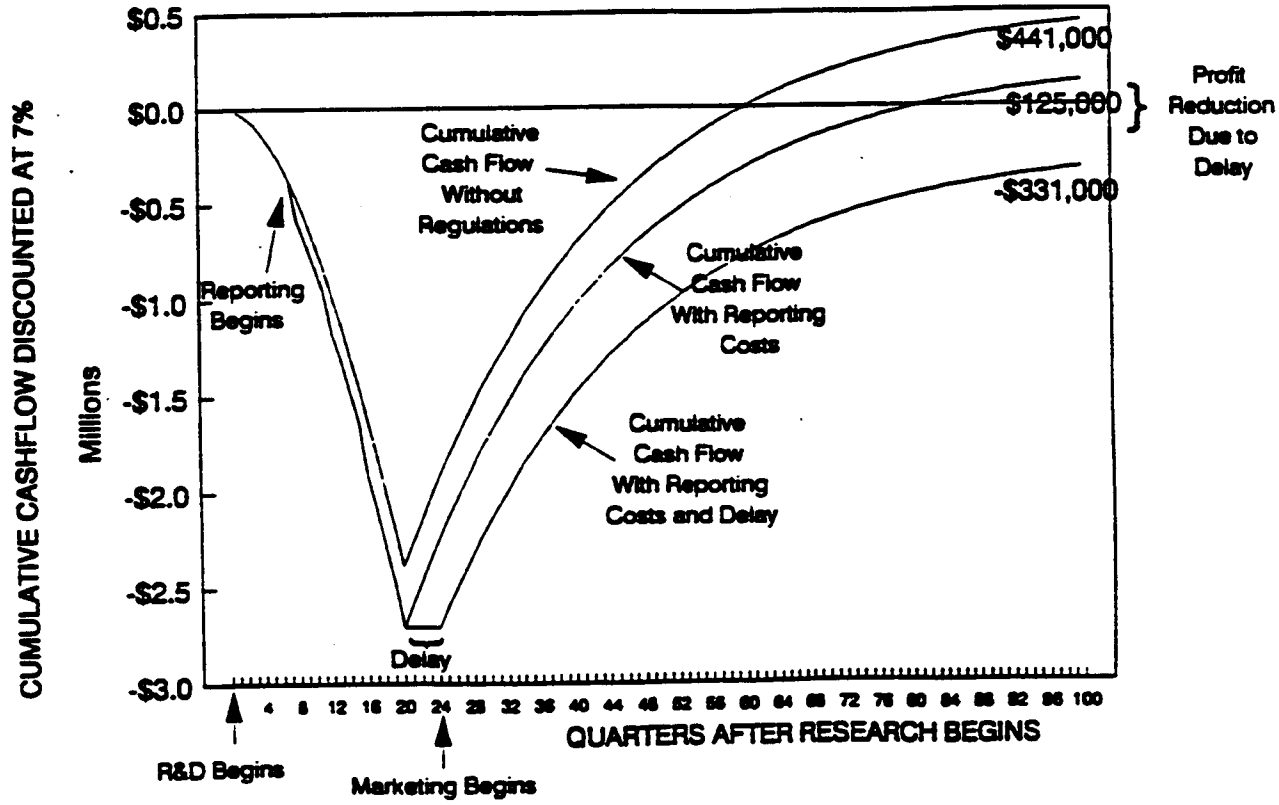


Figure F-2: Effects of Reporting Costs Plus Delay (Case 2)



Because of regulation, then, the project barely reaches profitability (a positive cumulative discounted cash flow) by the end of the period examined. It is projected to net a total of about $125,000, if costs and returns are discounted at a real (that is, inflation-adjusted) rate of 7 percent. Put in other terms, the reporting costs have pulled the IRR down from 9.7 percent to 7.7 percent, so that the project barely breaks even at the 7 percent discount rate. This project would not be canceled as a result of regulation, presumably, but would become even more marginal.

2. Case 2: Effects of Delays on a Non-exempt Environmental Application Project

Case 2 shows the additional effects of a regulation-caused delay in bringing the product to market. While products will not necessarily experience marketing delays as a result of regulation, this example assumes, for purposes of illustration, significant delays in marketing due to the time taken for regulatory review. In the development of a non-exempt environmental application product requiring extensive field tests, there may be considerable delays in commercialization as the firm submits multiple TERAs and a MCAN. The delays could be a combination of internal delays (that is, development delays while the firm is preparing reports for EPA) and external delays (while EPA is reviewing the reports, possibly combined with the bad luck of missing a seasonal window).

The lower panel of Figure F-2 (Case 2) shows how these delays could affect the discounted cash flow. The delay appears as a horizontal segment four quarters in length at the bottom of the cumulative cash flow curve. This

segment indicates a pause in the project between the end of the development phase and the start of the commercial period of positive cash flows.*

The cumulative cash flow curve is much lower if a delay is added to the reporting costs than if there are reporting costs but no delay. In fact, the delay by itself can be seen to push the cumulative discounted cash flow down by more than the reporting and control costs of $390,000 by themselves. The reporting costs pulled the cumulative cash flow down from a profit of $441,000 to a profit of $125,000, a reduction of $316,000.** The delay lowered the cumulative cash flow by an additional $456,000, which is greater than the impact from reporting costs.

While canceling the project would avoid the reporting and delay costs, it would lead to other costs, in the form of foregone profits. If the firm cancels the project before it starts, its loss is less than the sum of the discounted reporting and delay costs of $772,000 (discounted reporting costs of $316,000 and delay-related costs of $456,000). By canceling, only the net

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It is assumed that the obsolescence of the product continues during this period -- that is, other firms are assumed to continue their development of products that will eventually drive the new product out of its intended market niche and that changes in the market will continue to erode the niche itself. If obsolescence does not continue while the project is delayed, the effects of the delay can be greatly reduced. This could be the situation if the new product is kept secret during its development, is aimed at a long-lasting market niche, and is innovative enough so that competitors are unlikely to be able to start developing similar, competing products until they see it on the market.

For simplicity, the exhibit shows a case in which the entire delay occurs after development is complete. The more likely cases (in which the delays are spread throughout the process) have very similar effects on the firm's bottom line.

The reduction in the cumulative cash flow was less than $390,000 because of discounting; the reporting costs are not assumed to occur until three to five years into the project. In calculating the discounted cash flow for the project, the costs occurring in the third and fifth years are discounted back to the beginning of the project.

discounted returns of $441,000 are lost. Note that the loss does not equal the revenues of $6 million or so, only the foregone profits.

3. Cases 3 and 4: Effects on Small-scale and Large-scale Projects

The two previous cases concentrate on a non-exempt environmental application project of average magnitude in terms of its development costs. The full range of project magnitudes (even considering only environmental application projects with reportable microorganisms) is probably very broad, however, with many projects either much larger or much smaller than average. The expected returns from these projects probably tend to vary in the same manner (i.e., projects with higher costs tend to be associated with higher returns). To assess the effects of the rule-related costs on projects of different sizes, the preceding analyses were repeated for two additional projects. In terms of development costs and expected returns, the first is of a magnitude three times greater than the average case, while the second's magnitude is only 30 percent as great as average.

The results of these analyses are shown in Figure F-3 (Case 3 and Case 4). The upper panel of Figure F-3 (Case 3) shows the effects of regulatory reporting costs of $390,000 on the larger project, without a delay and with a delay of one year (Cases 3a and 3b, respectively). The lower panel of Figure F-3 (Case 4) shows the effects of the same regulatory costs and delays on a small project (Cases 4a and 4b). Because the reporting costs are constant in dollar terms, they loom much larger for the small project than the large one. The reporting costs barely affect the cash flow curve of the large project, which is profitable with or without them.

In contrast, the smaller project's finances would be devastated by the reporting costs alone.* These cases show that absolute costs are much more likely to cause an otherwise profitable project to be canceled if it is relatively small in magnitude -- with small expected returns. A corollary of this observation is that any one project lost as a result of increased reporting costs is not likely to have provided major private benefits.** On the other hand, small-scale projects can be expected to be more common than projects that are very large in magnitude, or even of average magnitude. The typical or median project is apparently considerably smaller than the average project; thus, reporting costs could potentially affect a significant portion of non-exempt environmental application products.

A very different pattern emerges when the effects of delays are examined. The upper panel of Figure F-3 reveals that the cash-flow implications of the delays are quite serious for the large project -- much more serious than the reporting costs. They reduce the cumulative discounted cash flow from about $1,000,000 to a negative $360,000, a swing of well over $1,000,000. By contrast, the same delay for the smaller project pulls the cumulative cash flow down by only about $140,000. The reason for the difference is that the delay has the same relative impact on the two projects, cutting out one year's worth of profits for each. A year's worth of profits is ten times greater in absolute terms for the larger project than the smaller. Delays of the same absolute length, therefore, could be as serious

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* In terms of the effect on the internal rate of return, reporting costs pull down the IRR for the larger project only from 9.7 percent to 8.7 percent; while the IRR for the smaller project is reduced from 9.7 percent to 4.2 percent.

** Some may have provided major social benefits. This is discussed in a later section of this chapter.

Figure F-3: Effects on a Marginally Profitable "Large-scale" Project (Case 3)

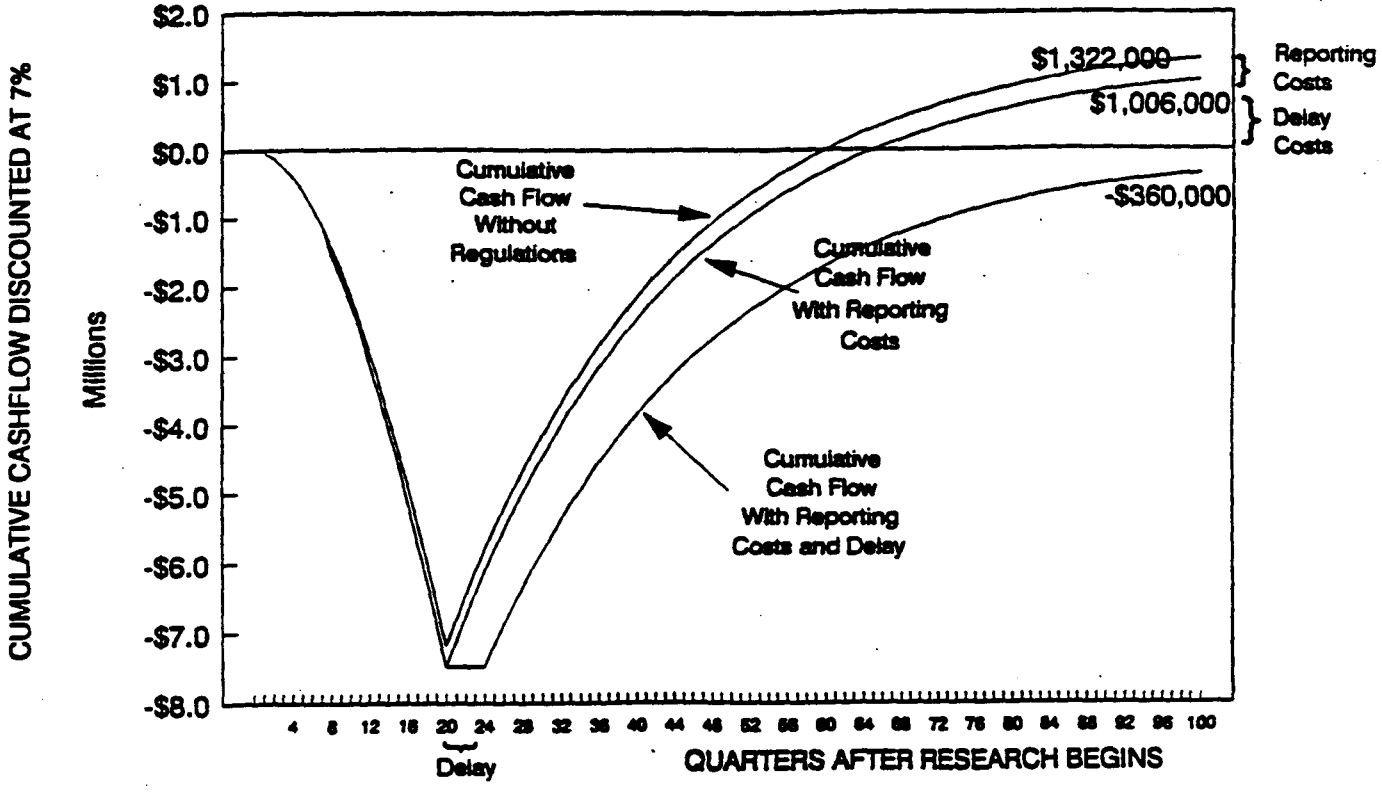
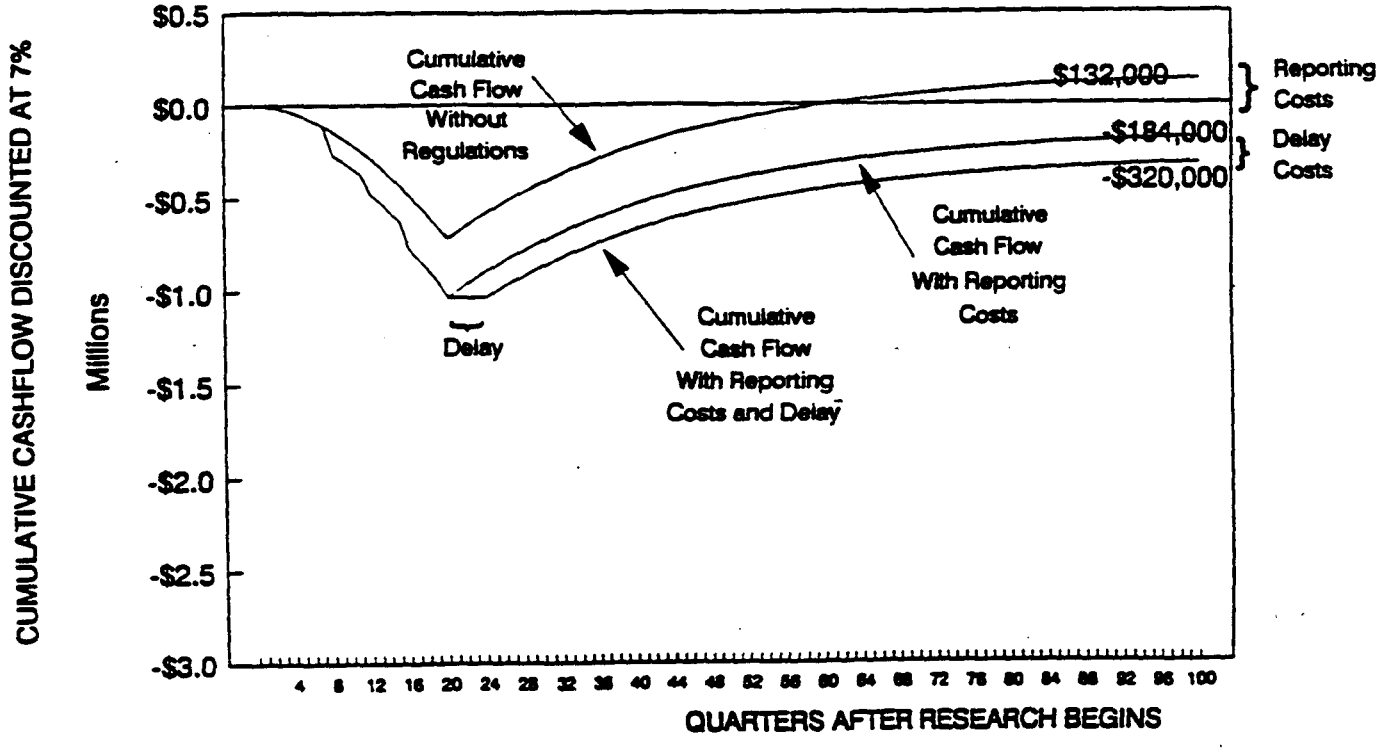


Figure F-3: Effects on a Marginally Profitable "Small-scale" Project (Case 4)



for large projects as for small ones in terms of rate of return. As the bulk of profits will probably be derived from the larger projects, the importance of delays becomes more apparent.

4. Case 5: Impacts of the Reporting Costs for High-Return Projects

The project examined in Case 1 is only marginally worth pursuing before the imposition of regulatory costs. Projects that appear, from the start, to be even less rewarding than this project are not likely to be pursued (unless there are special circumstances operating). Many projects, however, are likely to be considerably more promising than the project presented in Case 1.

This section examines the effects of $390,000 reporting costs, combined with either no delays or a one year delay, on a project with the same development costs but quarterly returns 50 percent greater than in Case 1. The project would have a cumulative discounted cash flow of $1,855,000 without regulations; $1,539,000 with reporting costs, and $856,000 with reporting costs and a one year delay. Thus, the project would not be canceled as a result of the reporting requirements, or even with the reporting added to a one year delay. One positive implication of this result is that the most promising projects (from a private, profit-making perspective) are those least likely to be eliminated as a result of the rule.

The delays, however, do have a very large impact on the absolute value of the project -- reducing the cumulative discounted cash flow by $683,000 compared to the $456,000 impact of the delay in Case 1 and Case 2. This impact, 50 percent greater than in Cases 1 and 2, is a direct consequence of the assumption of 50 percent greater quarterly returns for the more promising project. Again, delays affect net returns directly, and are proportionately

more serious in terms of absolute dollars when they affect proportionately more profitable projects.

5. Cases 6 and 7: Effects of Delays on Projects with Varying Rates of Obsolescence

Two other cases were examined in which the obsolescence rate (the rate of revenue decline) was changed from the 10 percent per year assumed for Case 1. In Case 6, the obsolescence rate was raised from 10 percent to 30 percent per year, while leaving development costs and the internal rate of return before regulations constant. The effects of the reporting costs were roughly the same in this case as in Case 1. The impact of a one year delay, by contrast, was almost doubled, to almost $800,000. This is not surprising, since a year's delay for a product with a short commercial life cuts out a very significant fraction of the product's returns. In the case of very slow obsolescence, the impact of a one-year delay was found to be considerably smaller than the impact in Cases 1 and 2. A possible implication is that products facing heavy technical competition from domestic or foreign suppliers not affected by the rule could face more severe profit impacts due to shorter product life cycles.

6. Case 8: Effects of Lower Regulatory Costs and No Delays on a Non-exempt Project

Some environmental application projects may have considerably lighter regulatory burdens than those examined above, especially if they involve few field tests or if subsequent tests are exempt from reporting. In the case of a project with the same magnitude as the average non-exempt project but with no regulatory delays and $38,000 in reporting costs, the project would still be profitable even with regulation, and thus probably would not be canceled. Even smaller projects (for example, projects with development costs and expected returns only a tenth as great as the average project) could still be profitable if there were no regulatory delays and

reporting costs of $38,000. Only very small projects--those with costs and returns more than an order of magnitude smaller than the average project--would become unprofitable with regulatory costs of this magnitude. Projects that are larger or more promising than average, on the other hand, would be very unlikely to be disrupted by these regulatory costs.

7. Case 9: Effects of Regulatory Costs on a Fermentation-system Non-exempt Project

The regulations are not expected to affect fermentation-system projects as severely as those aimed at creating environmental application products. Due to lower perceived risks and the absence of multiple field trials, a typical fermentation-system project that is just as great in magnitude as one developing environmental application products* might have reporting costs only a fraction as great. A fermentation-system project also is much less likely to be delayed as a result of the regulations, because of two considerations. First, R&D reporting is not required, and second, risk concerns are usually smaller, so that review is more likely to be completed in 90 days.

With reporting costs of $35,000 (equal to the expected costs for a fermentation-system product, as presented earlier in this appendix) and no delays, the average fermentation-system non-exempt project probably would not be canceled. In the model run, it remained profitable even after allowing for regulation. A second run assuming a project magnitude only one-tenth as great still showed that the project would not be canceled as a result of the rule. In fact, only the very smallest or least promising fermentation-system project would be made unprofitable as a result of a $35,000 reporting cost

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* Clear evidence on the magnitude of fermentation-system projects in comparison to environmental application projects was not available. However, we might expect environmental application microbial products to be more costly to develop because of the need for microorganisms that can function effectively under uncontrolled field conditions.

unaccompanied by delays. Again, projects larger or more promising than the typical project are even less likely to be made unprofitable by the regulations.

8. Case 10: Incentives for Shifts in Microorganisms or Process of Development

In some cases, companies may switch from reportable microorganisms to exempt microorganisms instead of canceling a project. This could be true even if regulations affect both techniques. A hypothetical example was constructed in which, in the absence of regulations, a reportable project with returns of $1,855,000 would be chosen over an exempt or excluded project with returns of $912,000 (in Table F-5, compare Case 5b to Case 10). The non-exempt project would be continued even with reporting costs and delays -- returns were calculated to drop to a net $856,000 after regulation -- unless the firm could shift its resources to the unregulated alternative project, returning $912,000.

Here the shift in the microorganism used cuts the regulatory impact by $56,000 ($912,000 in profits from the unregulated case 10 product versus $856,000 for the regulated case 5b product). Shifts of this kind are realistic possibilities, as illustrated on pages VI-2 and VI-3.